



Therapeutic Goods (Restricted Representations—Patient Health Organisations) Permission 2021

I, Nicole McLay, as delegate of the Secretary of the Department of Health, make the following permission.

Dated 12 May 2021

Nicole McLay
Assistant Secretary
Regulatory Compliance Branch
Health Products Regulation Group
Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—Patient Health Organisations) Permission 2021*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is made.	13 May 21

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 42DK of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

- (a) advertise;
- (b) therapeutic goods; and
- (c) Therapeutic Goods Advertising Code.

In this instrument:

Act means *Therapeutic Goods Act 1989*.

patient health organisation means an organisation that represents the interests of health care consumers, and includes an organisation that provides support and resources for health care consumers.

Note: This instrument does not apply to organisations mentioned in subsection 16(2) of the Therapeutic Goods Advertising Code, including hospitals and healthcare facilities, which are prohibited from endorsing therapeutic goods.

restricted representation means a representation referred to in section 42DD of the Act.

serious form, in relation to a disease, condition, ailment or defect, has the same meaning as in section 28 of the Therapeutic Goods Advertising Code.

5 Permission

For subsection 42DK(1) of the Act, in relation to each item mentioned in the table in Schedule 1, the restricted representations specified in column 2 are permitted to be used in the advertisements specified in column 3, about the therapeutic goods specified in column 4, subject to the conditions (if any) specified in column 5.

Schedule 1—Permission: restricted representation

Note: See section 5.

Permitted use of restricted representation				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Restricted representation	Advertisement	Therapeutic goods	Conditions
1	a representation that refers to the name of a patient health organisation, in circumstances where that name relates to, or can be taken to relate to, a serious form of a disease, condition, ailment or defect	<p>an advertisement about the therapeutic goods including, but not limited to, an advertisement that is:</p> <p>(a) on the label of the therapeutic goods;</p> <p>(b) on the package in which the therapeutic goods are contained;</p> <p>(c) on any material included with the package in which the therapeutic goods are contained</p>	<p>therapeutic goods for which:</p> <p>(a) there is an arrangement between the advertiser of the goods and the patient health organisation, which governs the use of the name of the patient health organisation in advertising; and</p> <p>(b) valuable consideration is being, or has been, given to the patient health organisation by the advertiser</p>	<p>both of the following:</p> <p>(a) the advertisement must include a statement to the effect that the endorsement is based on valuable consideration given to the patient health organisation; and</p> <p>(b) the advertisement must not contain a statement (expressly or by implication) that the patient health organisation otherwise endorses the therapeutic use of the therapeutic goods</p>

Note: An example of a statement to the effect that the endorsement is based on valuable consideration given to the patient health organisation may include a statement that the advertiser provides a portion of the proceeds from the sale of the goods to a specific patient health organisation.